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“Formulation Development and Evaluation of Phytoconstituents loaded proniosomal gel for Effective treatment of Psoriasis”

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1. ABSTRACT OF PROPOSED WORK PLAN/ PROBLEM :

The nanostructured proniosomal drug delivery system has been proven as a novel topical drug delivery system that is considered to significantly enhance the permeability, stability and retention time of drugs into deeper layers of the skin. The sparingly soluble or practically water insoluble phytoconstituents pose a challenge of poor skin penetration and to prepare its effective topical pharmaceutical formulation. The above problems can be overcome by the proniosomal gel formulation which can entrap both hydrophilic as well as hydrophobic phytoconstituents and its nano vesicular structure can help penetrate and deliver drug in deeper layers of the skin. The aim of the present study is to develop, optimize and evaluate nanostructured proniosomal gel loaded with a combination of phytoconstituents for the treatment of psoriasis. Compatibility of phytoconstituents and the excipients can be evaluated with Differential Scanning Calorimetry (DSC) analysis and Fourier Transform Infrared Spectroscopy (FTIR). The proniosomal gel of the individual phytoconstituents can be prepared by coacervation phase separation method respectively and characterized for its entrapment efficiency, viscosity, spreadability, pH, vesicle size, zeta potential, drug content and *In-vitro* diffusion study. The optimized batches would be selected on the basis of results of the characterization of the prepared formulations. The optimized proniosomal gels loaded with phytoconstituents are then mixed with carbopol matrix base. *Ex-Vivo* and *In-Vitro* drug release studies of the prepared proniosomal gels and plain gels incorporated with phytoconstituents will be carried with the help of Franz Diffusion Cell. Comparative animal studies will be carried to evaluate the therapeutic activity of plain gels of phytoconstituents and proniosomal gels of phytoconstituents individually and in combination. It will also be evaluated if combination of a phytoconstituents shows additive or synergistic effects.

Key words: Proniosomes, Gel, Phytoconstituents, Psoriasis.

2. INTRODUCTION :

Psoriasis is a widespread condition affecting millions of people worldwide. It is recognized as one of the most common chronic skin disorders, with varying prevalence rates across different regions and populations (1). The global burden of psoriasis is significant, not only due to its impact on individuals' physical health but also because of its social, emotional, and economic consequences (2, 3). Psoriasis affects about 2-3% of the global population, which equates to approximately 125 million people worldwide(4). Psoriasis is a chronic autoimmune condition that primarily affects the skin, causing the rapid growth of skin cells (4). This leads to the buildup of scales and red patches, which can be itchy, painful, and sometimes inflamed. It is a long-term condition that can vary in severity and often comes in flare-ups, where symptoms worsen periodically. The exact cause of psoriasis is not fully understood, but it is believed to be related to a combination of genetic, immune, and environmental factors(5, 6). Psoriasis often runs in families, suggesting a genetic predisposition. Several genes are thought to be involved, particularly those related to the immune system(7). It is an autoimmune disorder where the immune system mistakenly attacks healthy skin cells, speeding up the skin cell production process. Normally, skin cells grow and shed over about a month, but in psoriasis, the process happens in just a few days, leading to the buildup of skin cells. Infections (like strep throat), stress, skin injuries (such as cuts or sunburn), cold weather, smoking, and certain medications can trigger or worsen psoriasis.

There are several different types of psoriasis, each with distinct symptoms. The most common form, characterized by raised, red patches of skin covered with silvery-white scales is known as plaque psoriasis (8, 9). It typically appears on the elbows, knees, scalp, and lower back. Guttate Psoriasis has small, drop-shaped lesions that appear on the arms, legs, and torso, often after a bacterial infection like strep throat. Inverse Psoriasis is characterized by red, shiny lesions that appear in skin folds such as the armpits, groin, and under the breasts(10). Pustular Psoriasis is characterized by white pustules (blisters of noninfectious pus) surrounded by red skin. This type can affect small areas or cover large portions of the body(9). Erythrodermic Psoriasis is a rare, severe form that causes widespread redness and shedding of the skin in large sheets. It can be life-threatening and requires immediate medical attention(8). Nail Psoriasis affects the nails, causing pitting, discoloration, and separation from the nail bed. In some individuals, psoriasis is accompanied by joint pain, stiffness, and swelling, leading to psoriatic arthritis. This condition can affect any joint, but is most common in the fingers, toes, knees, and spine (8).

Psoriasis is a chronic condition that currently has no cure, but there are a variety of treatment options available to manage symptoms and control flare-ups. The goal of treatment is to reduce inflammation, slow the rapid growth of skin cells, and alleviate the physical and emotional impact of the disease (8).

It is treated by various ways depending on the severity of the disease. Treatment approaches like topical treatment with corticosteroids and retinoids, phototherapy and systemic allopathic and biologicals medications(11). Most of the treatment ways stipulated above are associated with various adverse drug effects and systemic co-morbidities. Hence, the topical treatment with phytoconstituents could be the better alternative approach for the psoriasis(11). But delivering the topically applied medication at the site of action is challenge to the formulation scientist. Amongst various vesicular drug delivery systems, proniosomal gel is one of the best formulations.

Proniosomal gel is a liquid crystalline (gel) formulation of non-ionic surfactants which is formed by dissolving a surfactant and a membrane stabilizer in a minimal amount of relevant organic solvent and aqueous phase(12). It does not require hydration prior to application on the skin for topical drug delivery(13). It can be mixed easily with bases like ointment, cream, emulsion and gel which can help in dilution of the active pharmaceutical ingredient and facilitate the application of the preparation on the skin. It possesses inherent potential to lessen the systemic side effects and to increase therapeutic effectiveness of the medicament(14). Poor solubility is a major physicochemical obstacle associated with most of certain phytoconstituents which can be overcome by developing a pro-vesicular drug delivery system like proniosomal gel. It is possible to incorporate both hydrophilic and hydrophobic phytoconstituents in proniosomal gel(15). Compared to liposomes, niosomes and other vesicular drug delivery systems proniosomal gel is physically more stable during its storage and transport(16). It contains lamellar, cubic phase and hexagonal liquid crystals which makes the preparation more elegant and imparts it transparency and high viscosity (17). Addition of water in proniosomal gel promotes interaction between water molecules and polar heads of the surfactant and ultimately results in enlargement of bilayer (18). These days proniosomal gel is a choice of topical drug delivery because of its unique advantages compared to niosomes and other vesicular formulations (19-21).

Many studies have explored the effectiveness and safety of herbal phytoconstituents for the topical treatment of the skin infections(22-24). But certain phytoconstituents are sparingly

soluble or practically insoluble in water which poses a major obstacle for its topical delivery(25-27). Formulating its proniosomal gel probably improves its penetration and retention in the deeper skin layers(20, 28, 29). In this study a combination of phytoconstituents is used to study the individual therapeutic effect of phytoconstituents and in combination respectively. The present research work will also help to study if the combination of phytoconstituents if shows additive or synergistic effect. Below is a list of phytoconstituents obtained from various plants used for the treatment of psoriasis in Table no. 01.

Table No. 01: List of phytoconstituents obtained from various plants used for the treatment of psoriasis (30)**.**

Herb name	Active ingredients	Important properties (in dermatology)
Aloe barbadensis (Aloe vera)	Contains anthraquinones, saponins, salicylic acid, steroids and mucopolysaccharides	Restoration properties, removing psoriatic plaques, and moisturizing effects
Curcuma longa (Turmeric)	Curcumin, demethoxycurcumin, curcuminoids, Bisdemethoxycurcumin	Anti-inflammatory, antimicrobial soothes skin condition
Azadirachtaindica (Neem)	Azadirachtin, B nimbin, salannin, nimbandiol, Ascorbic acid, nimbolide, nimbanene	Antibacterial, used in skin ulcers, anti-inflammatory
Avenasativa (Oats)	Linoleic acid, saponins, vitamins D, A & E, alkaloids, oleic acid	Improvements in skin dryness, moisturization & collagen synthesis, high properties
Ziziphusspina-christi (Christ'sthornjujube)	Alpha-pinene, flavonoids, essential oils, tannin	Anti-microbial, skin freshness, Improves the structure of epidermis
Tinospora cordifolia (Giloy)	Octacosanol, nonacosan-15-one, heptacosanol, tinosporidine, Giloin	Detoxifies skin, improve skin structure, antiaging
Allium sativum (Garlic)	Allicin, ajoene, allyl sulfides, vinyldithiins	Effective on psoriasis, skin aging and rejuvenation, antifungal, antiviral
Pinus eldarica (Afghan pine)	Germacrene, beta-caryophyllene, alpha-pinene, beta-pinene, Vitamin A, magnesium	Improving structure of damaged skin, prevents normal celldeath & antioxidants properties
Minnettia pinnata (karanj)	Bitter flavonoids, tannin, karanjin, ponganon & karanjachromene	Antibacterial, anti-inflammatory, helpful in skin problems like itching, bleeding, pain
Cactus (Cacti)	Ascorbic acid, vitamin E carotinoids, amino acid, antioxidants compound	Helps in hydration & keeps skin moisturized, treats redness & inflammation
Cydonia seed-mucus (Quince seed)	Vitamins, mucilage, tannins, triterpenes	Moisturizing, healing the skin wounds, filling skin
Silybum marianum (Milk thistle)	Silibinin, schristin, silidianin, isomeric, linoleic acid	Anti-inflammatory, antioxidants, antiaging

	flavonolignans, silymarin	properties
Rosa damascenea (Damask rose)	Beta-citronellol, trans-geraniol-hen eicosane, n-nonadecene	Antimicrobial, antibacterial, Anti-inflammatory, soothe skin
Arctium lappa (Greater burdock)	Mucilage, polyacetylenes, guaianolide-type & contain vitamins C, E, B3 & K	Antibacterial, Regenerative properties, and moisture supply too
Archillea millefolium (Yarrow)	Alkaloids, coumarins, flavonoids (apigenin,luteolin,quercitin) salicylic acid, volatile oil, tannins, sterols	Relaxing and healing of damaged skin, anti-inflammatory
Lavandula angustifolia (Lavender)	Linalool, linalyl acetate, geraniol, caryophyllene, lavndulyl acetate	Helps even skin tone, antibacterial, helps in wound healing
Glycyrrhiza glabra (Licorice)	Glycyrrhizinaci, isoflavones, triterpene sterols, coumarins	Rich in antioxidants, mayhelp fight bacteria that infect the skin
Matricaria chamomilla (Chamomile)	Apigenin, quercetin, patuletin, coumarin, essential oils, luteolin, terpene, bisabolol	Antiseptic properties, great for soothing various skin problems
Mahonia aquifolium (Oregon grape)	Berberine, berbamine, Oxyacanthine, alkaloids	Anti-inflammatory, reduce redness in psoriatic flares, antifungal
Coleus (Flame nettle)	Forskolin A, Forskolin B, Forskolin H, alpha-cedrene	Antimicrobial, anti-inflammatory,Skin condition such as eczema
Rubia cordifolia (Manjistha)	Quinones, iridoids, oleananes triterpenoid, Rubicordifolia, Alizarin, purpurin	Antioxidant property, Treat inflammation, itchiness, bleeding
Glycine max (Soybean)	Genistein	Anti-inflammatory, anti-oxidant properties and anti-proliferative activity
Aloe barbadensis (Aloe Vera) *Aloe perryi* (Socotrine Aloe) *Rheum rhaponticum* (Rhubarb)	Aloe-emodin	Induce apoptosis, anti-inflammatory, anti-viral, anti-proliferative, analgesic and wound healing

3. REVIEW OF LITERATURES

Literatures were reviewed with the help of internet, and referring scientific journals and books. The survey reveals that, the present study has not been undertaken till date.

- **Yadav *et al.*, (2024)** stated that nanopolyherbal formulations offer significant benefits in the treatment of psoriasis, particularly when combined with modern drug delivery systems that minimize adverse effects. The distribution, efficacy, and safety of these novel drug delivery systems must be thoroughly evaluated for optimal therapeutic impact. Combining natural products with biologic treatments holds promise for treating both mild and severe psoriasis, but the mechanisms of action need careful study. Challenges such as low drug loading, stability, and encapsulation efficiency have hindered clinical trials. More research is needed to address these issues and explore preclinical studies with diverse animal models. While most current treatments target mild to moderate psoriasis, the future of precision medicine and targeted therapy may offer more effective solutions, potentially focusing on specific genes or cells for personalized treatment (30).

- **Motawea *et al.*, (2024)** developed transferosomal hydrogel incorporating genistein to enhance its bioavailability for melanoma treatment. The formulation was evaluated for particle size, polydispersity index, zeta potential, encapsulation efficiency, and various characterization techniques (TEM, FTIR, DSC, XRD). In vitro drug release, viscosity, pH, and ex vivo anti-tumor activity on 3D skin melanoma spheroids were also assessed. The optimized formulation demonstrated superior encapsulation efficiency, improved skin penetration, and prolonged drug release. Genistein, when loaded into transferosomes, exhibited enhanced anti-tumor efficacy, particularly in melanoma spheroids. Stability studies confirmed the formulations' chemical and physical stability, highlighting the potential of the genistein transferosomal hydrogel for effective cutaneous melanoma treatment (31).

- **Yassin *et al.*, (2024),** fabricated fluconazole loaded proniosomal gel by using an appropriate combination of surfactants ie; span 60 and tween 80 (1:1). Prepared proniosomal gel was evaluated for In vitro studies and showed better release pattern. Other studies like entrapment efficiency, particle size and zeta potential shown better result with sustained release of encapsulated fluconazole proniosomal gel(32).

- **Darson *et al*., (2023),** prepared proniosomal gel of Doxorubicin and Indocyanine Green. It was evaluated for drug content, zeta potential, vesicle size, invitro drug pattern. The drug release and kinetic studies of the optimized proniosomal gel showed a control release pattern. The prepared proniosomal gel exhibited excellent formulation characteristics. The results of cytotoxic study using HeLa cell lines presented cytotoxic effect for optimized proniosomal gel(33)

- **Hassan *et al*., (2022),** the study aimed to fabricate and optimized Curcumin-based proniosomal nanocarriers as an antiviral agent. The phytoconstituent based proniosomes were optimized by 3^2 factorial design and method used slurry method with effect of different variables. The prepared and optimized batch showed good %EE, stability and drug release. It could be the promising and stable carrier for curcumin showed effective antiviral activity and the safety of antiviral agent(34).

- **Garbiec *et al*., (2022)** recognized Genistein for its health benefits, is considered a functional food due to its multidirectional biological effects, which are attributed to its structural similarity to various cell receptors. Numerous in vitro and animal studies highlight its potential therapeutic benefits in conditions like non-alcoholic fatty liver disease, psoriasis, cataracts, and cystic fibrosis. However, the limited animal data that can be directly applied to humans, due to the complexity of isoflavone metabolism and variations in bioavailability, remains a challenge. Additionally, genistein's low oral bioavailability restricts its practical use. The health benefits of soybean consumption are largely dependent on the isoflavone content and metabolically active compounds, and population variability should be considered when studying its effects on specific diseases (35).

Reesha *et al*., (2022), formulated Amphotericin B proniosomal gel for topical treatment by simple coacervation phase separation technique by surfactant (non-ionic), lecithin and membrane stabilizer as cholesterol. The proniosomal gel was charecterized for their % encapsulation, pH, content uniformity, viscous nature, extrudability, release pattern, permeability and stability. The prepared proniosomal exhibited good formulation characteristics. The results of evaluation were found within the adequate ranges(36).

- **Schwarz *et al*., (2021),** explored the alteration of T regulatory cells (Treg) in psoriasis, highlighting the potential link between Treg frequency and cytokine changes. While it remains

unclear whether Treg changes contribute to or result from psoriasis' pathophysiology, epigenetic regulation appears to play a role in modulating Treg function. Notably, acetylation of H3 histones was found to be lower in Treg from psoriasis patients compared to healthy controls. Sodium Butyrate (SB), a known histone deacetylation inhibitor, has been shown to restore histone acetylation and stimulate antibacterial defense. This suggests that Short-Chain Fatty Acids (SCFA), which may regulate Treg function, could offer therapeutic potential for psoriasis. Further research on the topical application of SCFA is needed to assess their effectiveness in treating psoriasis (26)

- **Bochenska *et al*., (2021)** evaluated the therapeutic potential of Genistein for treating mild to moderate psoriasis through in vitro and in vivo research. The clinical trial showed that Genistein reduced both clinical and biochemical scores in patients, with no significant adverse events, dose-limiting toxicities, or treatment discontinuations. Blood interleukin levels notably changed, and psoriatic lesions exhibited regression. In vitro, Genistein inhibited the activation of MAPK, NF-κB, and PI3K pathways in human epidermal keratinocytes induced by IL-17A and TNF-α. It also reduced the expression of psoriasis-related genes and key cellular signaling pathways. These findings suggest that Genistein is a promising therapeutic option for psoriasis, potentially beneficial in combination with other treatments (37).

- **Shehata *et al*., (2021),** formulated proniosomes composed alone with surfactant or in combinations of surfactant like Span 60 along with Tween 80 and membrane stabilizer cholesterol. The niosomes fitted specific model with non-Fickian transport which showed vesicular release of formulations deposited higher active constituents release amounts of curcumin in the skin as compared to other formulation like suspension form. On the basis this study of preparation and evaluation parameter it revealed that the formulated vesicular emulgel system has potential to effectively show the anti-inflammatory action of active drug by transdermally delivering curcumin encapsulated in a vesicle(38).

- **Shah *et al*., (2021),** evaluated the impact of various formulation components, such as drug content, surfactant type and quantity, and excipients like cholesterol and lecithin, on the characteristics of proniosomal gels. The results revealed that these ingredients significantly influenced the appearance, vesicle size, and other properties of the gel. (39).

- **Eltellawy *et al*., (2021),** formulated Atorvastatin Calcium (ACT) loaded proniosomes for transdermal administration with the goal of evaluating their anti-hyperlipidemic and hepatotoxic effects. The results of the penetration experiment presented that, in relation to ATC in free form, proniosomes greatly increased ATC diffusion across the rat skin. Measurement of liver biomarkers and histological analysis indicated that transdermal proniosomes were superior in removing the hepatotoxicity linked to oral delivery. In order to prevent adverse effects after oral treatment, our work suggests that transdermal proniosomes of Atorvastatin Calcium may be useful in the treatment of hyperlipidemic patients having hepatic disorders(40).

- **Ahmed *et al*., (2021),** formulated a proniosome gel loaded with fluticasone propionate, exhibiting a high entrapment efficiency. By adding xanthan gum the drug residency at the administration site was prolonged. Following inclusion, it was demonstrated that the resulting mucoadhesive proniosome gel had optimal gel strength, good mucoadhesion force, outstanding organoleptic property, and sustained release for almost six hours. The findings of the MTT cytotoxicity assay presented results which were within safe range. On the basis of the histological results and an in vivo efficacy investigation, fluticasone propionate mucoadhesive proniosome gel would be a useful treatment for oral ulcerative lesions(41).

- **Khan *et al*., (2021),** stated that herbs have long been recognized for their health benefits with minimal side effects, and the integration of phytoconstituents into nanocarriers holds significant potential in advancing nanophytomedicine. This emerging field enhances the efficacy of herbal remedies by overcoming traditional limitations. Nanophytomedicine not only boosts the biological activity of herbal medicines but also improves the effectiveness of nanotherapeutic products. By increasing treatment efficacy and reducing healthcare costs, nanophytomedicine presents a promising approach for treating a variety of diseases. Given the vast potential of plant science in addressing serious illnesses, nano-formulations incorporating phytoconstituents warrant focused attention for future therapeutic applications (42).

- **Pinzaru *et al*., (2021),** prepared proniosomal gel by simple mixing of ingredients for cutaneous applications. The formulated gel was evaluated for zeta potential of vesicle, % encapsulation capacity, vesicular particle size, pH and rheological properties. The study showed better results with high biocompatibility and a lack of irritation and phototoxicity potential. The prepared proniosomal gel exhibited good formulation characteristics. It concluded that fabrication of vesicular formulation of proniosomes is an effective treatment for skin diseases(43).

- **Pandey *et al.*, (2021)** prepared Cyclosporine-loaded niosomes gel using the film hydration method and characterized for encapsulation efficiency, viscosity, and texture. The optimized niosomes demonstrated significantly improved permeation (50.57% in 24 hours) compared to cyclosporine solution (10.13%) in ex vivo permeability tests on albino rat abdomen skin. Fluorescence microscopy with Coumarin 6 revealed 59-fold higher deposition of cyclosporine in the dermis and epidermis layers when delivered via niosomes. Histological analysis and PASI scores showed that niosomes significantly reduced psoriasis severity compared to cyclosporine suspension gel. These findings suggest that cyclosporine-loaded niosomes can enhance skin penetration and improve psoriasis treatment efficacy (44-46).

- **Pradhan *et al.*, (2021)** successfully loaded Fluocinolone acetonide (FA) into nanostructured lipid carriers (NLCs) using a microemulsion technique for psoriasis treatment, and salicylic acid (SA) was incorporated into a carbopol 934 gel base. A factorial design was used to optimize the formulation. In vitro characterization revealed similar pH values (6.2 ± 0.22 for FA-SA-loaded gel and 6.3 ± 0.10 for plain FA and SA-loaded gel), with high drug content (98.72% FA and 98.13% SA in the FA-SA gel). Confocal microscopy showed that FA from the plain gel primarily localized in the epidermis, whereas NLC-enriched gel exhibited superior skin distribution. The study concludes that the NLC-enriched gel formulation is more effective than conventional gel formulations for psoriasis treatment (47).

- **Bhardwaj *et al.*, (2020),** stated that niosomes offer a controlled, consistent, and targeted drug delivery system, gaining popularity for their ability to simultaneously encapsulate both hydrophilic and hydrophobic drugs. They can encapsulate a wide range of medications, including natural products, enzymes, peptides, DNA, vaccines, and anti-cancer agents. In addition to offering flexible administration routes, niosomes provide a non-toxic alternative to liposomes, making them a superior choice for drug delivery. Given these advantages, ongoing research into niosomes is expected to lead to effective pharmaceutical formulations with significant market potential (48-50).

- **Aboali *et al.*, (2020),** successfully formulated a proniosomal gel using coacervation phase separation method, achieving a mean vesicle size of 212 nm and a high entrapment efficiency (EE) of 96%. SEM analysis revealed smooth, compact vesicles, and the formulation demonstrated improved ex-vivo ocular permeability, with a 3.2-fold increase compared to CUR. Histopathological evaluation confirmed its safety profile. The results suggest that

Cremophore-based nonionic surfactant proniosomal gels are a promising carrier for enhancing ocular CUR delivery, offering better penetration, high biocompatibility, anti-inflammatory efficacy, and fewer side effects compared to traditional ocular corticosteroid treatments (18, 51).

- **Akbari *et al*., (2020),** in this study, the lipophilic medication curcumin was effectively added to a mixture of surfactants and cholesterol to create niosomes for transdermal administration. Due to a higher percentage of cell survival of 90%, an in vitro cytotoxicity evaluation of the improved curcumin-loaded noisome indicated no harm. As a result, this tactic might be considered one of the more successful options for applying curcumin topically as well as transdermally. Furthermore, the niosomal gel component that was used showed no signs of irritation according to the skin irritation test. The curcusome formulation exhibited stronger anti-inflammatory and antinociceptive actions, as indicated by the results of the tail-flick and formalin test(52).

- **Shah *et al*., (2020),** investigated and evaluated the transdermal delivery of tramadol proniosome for its therapeutic activity. The prepared and optimized proniosome gel was evaluated for different evaluation parameter drug release studies, stability and animal study which presented good results with and on the basis of evaluation the improvement in anti-inflammatory effects as well as antinociceptive effects were observed. It could be the favorable alternative therapy on oral administration of tramadol which is having a greater efficacy(53, 54).

- **Sarfaraz *et al*., (2020),** formulated Galantamine hydrobromide proniosome gel by CPS method as it shows severe side effects in oral drug delivery. Transdermal administration of the proniosomal gel formulation has been effective in treating Alzheimer's disease. In this study non-ionic surfactant (tween) showed a higher drug release than other non-ionic surfactants like spans(55).

- **Bisht *et al*., (2019),** examined topical vesicular of piroxicam since oral piroxicam administration has serious adverse effects on the gastrointestinal tract. The niosome containing piroxicam was prepared by the film hydration process. This will contribute to extending the drug's duration of residence in the skin layer, hence augmenting its anti-inflammatory properties(56).

- **Sammour *et al*., (2019),** has developed proniosomal aceclofenac proniosomes with different carriers like mannitol, maltodextrin, and glucose. The batch of proniosomes was optimized by using maltodextrin as a vesicular carrier. The obtained results concluded that the suitable method of preparation for proniosomes was slurry method which successfully prepared an aceclofenac proniosomes with different carriers(57, 58).

- **Shah *et al*., (2019),** formulated, optimized and compared lornoxicam proniosomal gel with oral formulation as lornoxicam showed lower solubility and GIT adverse effects. The optimized drug loaded proniosomal gel were evaluated and showed better % entrapment efficiency, greater transdermal delivery, zeta potential and stability studies of prepared formulation. It demonstrated the improved therapeutic effect of lornoxicam than that of the oral treatment(29).
- **Gugleva *et al*., (2019),** developed a variety of cholesterol- and nonionic surfactant-based niosomes as potential nanoscale doxycycline hyclate delivery methods for ocular application. Niosomes having (span 60:cholesterol) in ratio 6:4 had shown excellent entrapment efficiency, slower release rate and appreciable formulation characteristics. The analytical results suggest that the prepared formulation is a feasible basis for doxycycline hyclate opthalmic administration(59).

- **Qiao *et al*., (2019),** the present study revealed that suggest that mechanical stretch promotes keratinocyte activation and proliferation, in line with other studies. In order to replicate the real-world milieu of keratinocytes under mechanical stretch, a skin expansion mouse model was used for the study. The findings offer novel information about the pathophysiology of psoriasis by suggesting that mechanical strain influences keratinocyte proliferation along with its effect on cytokine expression in the skin keratinocytes cells(60).

- **Divya *et al*., (2016)** in this study developed a chitin-based nanogel system for transdermal delivery of Acitretin and Aloe-emodin for psoriasis treatment. Particle size was optimized by adjusting probing time and amplitude, with the best systems selected based on entrapment efficiency. Characterization confirmed nanoscale spherical particles with intermolecular hydrogen bonding. The nanogels exhibited thixotropic behaviour, pH responsiveness, and sustained drug release at acidic pH. In vitro and in vivo studies demonstrated enhanced skin penetration, better drug retention in deeper layers, and anti-psoriatic activity. The system's biocompatibility was confirmed by histological analysis. These findings suggest the nanogel system as an effective treatment for psoriasis (61)

4. CHARACTERIZATION OF RESEARCH GAPS

- There is scope to develop a proniosomal gel formulation for a combination of phytoconstituents owing to it advantages compared with conventional and other vesicular drug delivery systems.
- A combination of phytoconstituents can show an additive or a synergistic effect.
- Use of a combination of surfactants can result in a stable and efficient proniosomal gel.
- Use of a combination of a membrane modifiers and stabilizers can produce a more stable and uniform nano vesicles.
- No study has been yet reported for a combination of a phytoconstituents in the form of proniosomal gel for the treatment of the skin infections.

5. AIM AND OBJECTIVES :

The current study aims to develop and optimize proniosomal gel loaded with phytoconstituents for the treatment of psoriasis. The study also aims to evaluate the therapeutic potential of phytoconstituents based proniosomal gel by using imiquimod-induced psoriasis model. Additionally, the study evaluates the impact of combination when both phytoconstituents are used in combination in proniosomal gel form for the treatment of psoriasis.

OBJECTIVES :

- To select the effective phytoconstituents.
- To study compatibility of the phytoconstituents and the excipients.
- To formulate phytoconstituents loaded proniosomal gels.
- To incorporate optimized proniosomes containing phytoconstituents in the gel base matrix.
- To characterized and optimize the prepared phytoconstituents loaded proniosomal gels.
- To perform skin irritation study of the prepared proniosomal gel formulation
- To perform animal study by using imiquimod-induced psoriasis model.

6. MATERIALS AND METHODOLOGY TO BE ADOPTED MATERIALS:

Drug: Phytoconstituents

Surfactants: Span 20, 40, 60, 80 or Tween 20, 40, 60, 80 etc

Polymers: Gelling Agent.

Membrane modifiers and stabilizers: Cholesterol, Soya lecithin etc.

Preservative: Methyl paraben, Propyl paraben etc.

Other chemicals: Triethanolamine, water, ethanol, methanol, chloroform etc.

Instruments: Weighing balance, FTIR, pH-meter, Magnetic stirrer, SEM, UV Spectroscopy, Franz Diffusion Cell, Centrifuge, Brook field viscometer Sonicator Stability chamber, Differential Scanning Calorimetry, Refrigerator etc.

7. RESEARCH WORK PLAN:

- Literature survey
- Procurement of the drugs and excipients

- **Preformulation studies**
  - Solubility
  - Melting point
  - FT-IR study
  - Differential scanning colorimetry (DSC)
  - Calibration curve of pure drug
  - Analytical method (UV Spectroscopy).

- **Formulation of proniosomal gel**

  Proniosomal gel is prepared by coacervation phase separation method or different preparation method by using a combination of surfactants, the procedure is described in details as follows,

- **Experimental methodology**

  - Formulation and optimization of the proniosomal gel of phytoconstituents by coacervation phase separation method.
  - Incorporate optimized proniosomes of phytoconstituents in gel base matrix.
  - Determination of vesicle size and shape
  - Drug entrapment efficiency of proniosomal gel
  - Determination of Zeta potential
  - Drug-content study
  - Spreadability

- Viscosity measurement
- pH measurement
- In vitro drug release studies
- Ex-vivo skin permeation studies
- Skin irritation test
- Drug Retention studies
- In vivo anti-psoriatic activity study using imiquimod-induced psoriatic mouse model
- Stability studies

8. NEED OF THE PRESENT RESEARCH WORK

There is no exact cure for psoriasis. However, available treatments can often significantly reduce psoriasis symptoms. Treatments with allopathic medicines is associated with several adverse drug reactions and systemic or physiological comorbidities. Treatment with biologicals is effective but that is very expensive. Several studies have revealed that phytoconstituents are very effective in the treatment of psoriasis and less likely to be associated with adverse effects and other comorbidities. There is need of developing an effective topical formulation of phytoconstituents. Very few studies have experimented nanovesicular phytoconstituent delivery via proniosomal gel formulation for the treatment of psoriasis. No study has yet been reported for combination of phytoconstituents loaded proniosomal gel formulation for the treatment of psoriasis. Nanovesicular proniosomal gel is one of the best vesicular systems which offers better entrapment, vesicular stability, delivery in deeper layer of skin and increased retention time at the site of action. Hence the present research work has potential to develop a phytoconstituents loaded nanovesicular proniosomal gel formulation which may offer an safe, effective and alternative treatment for psoriasis.

9. IMPORTANCE OF STUDY/ SOCIETY APPLICATION

- Mostly the systemic treatments used for the treatment of psoriasis includes retinoids, steroids, allopathic drugs and biologicals are very expensive.
- The systemic treatments are mostly associated with severe adverse drug interactions and various comorbidities may arise after long term treatment.
- There in no specific cure to psoriasis.
- The topical phytoconstituents can be the cost effective and rationalistic treatment compared to the ADRs and comorbidities associated with systemic treatment with marketed formulations.

- The invention of proniosomal gel has becomes a significant step towards overcoming the problems associated with conventional drug therapy.
- The proniosomal gel formulation offers better entrapment and stability compared to other vesicular drug delivery systems.
- Nano vesicles could penetrate in deeper layer of the skin.
- Entrapment of phytoconstituents in the vesicles could increase the retention time of the phytoconstituents at the site of action.
- Treatment with combination of phytoconstituents may show an additive or synergistic effect.

10. INTERNATIONAL STATUS / NATIONAL STATUS

- Psoriasis is a chronic, autoimmune skin disorder affecting millions of people worldwide. It is a significant public health concern due to its prevalence, impact on quality of life, and the associated comorbidities such as cardiovascular disease, diabetes, and depression.
- Global Prevalence: Psoriasis affects about 2–3% of the global population, with varying prevalence rates depending on geographical regions. It is more common in Europe and North America, with lower prevalence rates observed in parts of Africa and Asia.
- Age and Gender Distribution: Psoriasis can develop at any age, but it typically appears in two peaks: in young adults (20-30 years) and in older adults (50-60 years). It affects both genders, although some studies suggest a slightly higher prevalence in men in certain regions.
- Impact on Quality of Life: Psoriasis is not just a skin disorder but can significantly impact emotional well-being, social interactions, and self-esteem. The disease has been associated with significant disability due to symptoms such as itching, pain, and the visibility of skin lesions.
- Comorbidities: Psoriasis is associated with several comorbid conditions, including:
  - Cardiovascular diseases: Individuals with psoriasis have a higher risk of heart attacks, strokes, and hypertension.
  - Metabolic disorders: Conditions like diabetes and obesity are more prevalent in individuals with psoriasis.
  - Psychological Impact: Psoriasis often leads to depression, anxiety, and social isolation, further affecting the patient's mental health.
- Access to Treatment: While treatments for psoriasis have advanced, access to therapies

remains uneven worldwide. In developed countries, biologic treatments have become a mainstay, but their high cost limits their availability in low- and middle-income nations.

- Management and Research:
  - Treatment: Psoriasis treatment varies according to disease severity, with options including topical treatments (corticosteroids, vitamin D analogs), phototherapy, systemic medications (oral drugs and biologics), and newer targeted therapies.
  - Biologics: The emergence of biologic treatments has transformed psoriasis management. Drugs such as TNF inhibitors (e.g., adalimumab), IL-17 inhibitors (e.g., secukinumab), and IL-23 inhibitors (e.g., guselkumab) offer targeted and effective treatment options for moderate to severe psoriasis.
  - Ongoing Research: Continuous research focuses on understanding the underlying immune mechanisms of psoriasis, improving therapies, and identifying new treatment targets. Genetic studies are shedding light on the hereditary aspects of the diseases.

11. RATIONAL OF THE STUDY

In proposed work, the proniosomal gel formulation will be prepared by incorporating proniosomes of individual phytoconstituents in gel base matrix for the treatment of skin diseases. By using a proper combination of surfactants and varying the concentration of cholesterol and lecithin it is possible to achieve the good entrapment efficiency, vesicular size and a stable formulation. Proniosomal gel formulation probably improve the penetration and retention of phytoconstituents in deeper layer of the skin which consequently enhance the therapeutic efficacy at the site of application. The developed formulations will be one of the best and economic option for the treatment of the psoriasis with very less or no adverse effects owing to user of herbal phytoconstituents. Very few formulations are being prepared using combination of phytoconstituents in nanostructured vesicular drug delivery system for the treatment of topical skin diseases. Expected additive or synergistic effect, increased skin permeation, retention at the site of action, sustain release of the phytoconstituents could change the course of treatment of the psoriasis.

12. PROPOSED WORK PLAN

Sr. No.	Expected target to be achieved	1-6 Months	7-10 Months	11-22 Months	22-27 Months	28-33 Months	34-36 Months
1	Literature survey	Literature survey					
2	Selection and collection of drug and excipients	Selection and collection of drug and excipients					
3	Formulation, development and optimization	Formulation, development and optimization					
4	Evaluation	Evaluation					
5	In vitro and in vivo study	In vitro and in vivo study					
6	Statistical Analysis, Data Interpretation and Conclusions	Statistical Analysis, Data Interpretation and Conclusions					
7	Publishing Research and submitting data	Publishing Research and submitting data					

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